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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,125	08/05/2003	Kazunobu Okazaki	Q76820	5755

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EXAMINER	
QAZI, SABIHA NAIM	
ART UNIT	**PAPER NUMBER**
1628	

NOTIFICATION DATE	DELIVERY MODE
03/17/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/634,125	OKAZAKI ET AL.	
	Examiner	Art Unit	
	SABIHA QAZI	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,11,13-15 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10, 11, 13-15, and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/03/11,04/09/08, 04/13/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Non-Final Office Action

Claims 10, 11, 13-15 and 18-20 are pending. No claim is allowed. Amendments are entered.

Summary of this Office Action

1. Information Disclosure Statement
2. Copending Applications
3. Specification
4. 35 USC § 103 Rejection
5. Double Patenting Rejection
6. Response to Remarks
7. Communication

Information Disclosure Statement

Please find enclosed copies of the IDS filed on 01/03/11, 04/13/07 and 04/19/08 with this office action.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See Dayco Products Inc. v. Total Containment Inc., 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 103-1st Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham **v.** John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 11, 13-15 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over EMOTO, MITSUO (US Patent 6,458, 395), DAVENPORT et al. (J. Dairy Sci. 83:2819; 892 reference), Yoshie et al. JP 2001-346528 (ABSTRACT AND English translation, 892 reference dated 10/05/10) and Mamoru JP 07-322817 (Abstract and English translation, 892-reference dated 10/05/10). The references teach a composition and process of making a nutritional supplement using whey protein, hydrogenated soybean, organic acids, vitamin D

and various other ingredients, which embraces presently claimed invention. See the entire documents.

Determining the scope and contents of the prior art.

Applicant's claim 10

10. (currently amended): A method for increasing plasma volume, plasma total protein content and plasma albumin content, comprising administering to a subject in need thereof, a gel composition comprising the following components and having a pH in the range of 3 to 4:

Protein that does not coagulate at pH 3 to pH 4	3 - 8 wt.%
Calcium in a natural calcium material	0.1 - 0.5 wt.%
Acids	0.5 - 3 wt.%
Carbohydrate	4 - 20 wt.%
Fat	0 - 0.3 wt.%
Emulsifying agent	0 - 0.02 wt.%
Agar	0.1 - 1 wt.%
Water	65 - 90 wt.%,

wherein said protein that does not coagulate at pH 3 to pH 4 consists of: (1) whey protein concentrate, a whey protein isolate, or desalted whey; and (2) ~~protein~~ gelatin hydrolysates having a number average molecular weight of 500-10,000.

EMOTO teaches that the proteins can be used singly or in combination. See lines 42-54 in column 4gelled foods and processes for producing such foods by using gelling agents. when specific amounts of lipid, saccharide, organic acid, organic acid salt, emulsifying agent and gelling agent are added to a protein so as to obtain an emulsion having an acidic pH equal or close to the isoelectric point of the protein, a composite of an isoelectric gel of the protein and a gel formed with the gelling agent is obtained, which is soft and homogeneous and capable of being swallowed without chewing.

a. The reference teaches a gel of an emulsified mixture comprising 10 to 50 wt. % of the combined amount of the ingredients listed below (on a dry weight basis) and 50 to 90 wt. % of water, and which has a **pH of 3.3 to 4**, and which is a composite of an isoelectric gel of the protein and a heat-soluble gel formed with the gelling agent and **good storage stability because of its pH of 3.3 to 4**, preferably 3.5 to 4. Moreover, in spite of the acidic pH, the food product of the invention is free from grains of **coagulated protein,** and has smoothness and homogeneity that impart good eating qualities and textural properties to the food product. The ingredients and proportions of the gelatinous food product of the invention are described in the references, (see the abstract and lines 4-10 in

column 3).

The gelatinous food product of the invention has good eating qualities and can be safely eaten by patients with dysphagia associated with various diseases or following surgical operations, the food product being capable of supplying well balanced nutrition. Further, the reference teaches that food product is suitable for not only the patients but also healthy people, for example, athletes who need to obtain nutrition quickly during training or competition.

Emoto teaches a nutritionally balanced gelatinous food product which is a composite gel formed with protein and about 0.2 to 5% of a gelling agent such as agar, guar gum, pectin, furcelleran, carrageenan, locust bean gum, Arabic gum or a combination thereof (Abstract, C5/L24-26). Emoto teaches that gelling agents have gelling and gel- stabilizing ability (C5/L26-28). Emoto teaches the addition of about 0.2 to about 5% of an agar and guar gum gelling agent combination, the reference does not explicitly disclose 0.1 to 1.0% agar. As gel texture is a variable that can be modified, among others, by adjusting the ratio of gelling agents, the precise concentration of agar and guar gum in the gelling agent combination would have been considered a result effective variable by one of ordinary skill in the art at the time of the invention. As such, without showing unexpected results, the

claimed concentration of agar or guar gum in the gelling agent combination cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have adjusted, by routine processing, the concentration of agar and guar gum in the gelling agent combination of modified Fuchs et al. to obtain the desired texture characteristics (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223).

The reference further teaches that the protein, one of the essential ingredients of the gelatinous food product of the invention, is selected from ones conventionally used in the field of food products. It is necessary that the protein form an isoelectric gel at the pH of the food product of the invention, i.e., pH 3.3 to 4. Examples of such proteins include gelatin, casein, whey proteins (e.g., lactalbumin), soybean protein and wheat protein; salts of these proteins; decomposition products (acid decomposition products and enzyme decomposition products) of these proteins; extracts of these proteins; concentrates of these proteins; and whole milk powders and skimmed milk powders. The proteins may

be used singly or in combination. The protein is present in the food product of the invention in a proportion of about 2 to 60%, preferably about 10 to 45%, more preferably about 15 to 30% on a dry weight basis. Proportions less than 2% or more than 30% are not preferable, since the resulting food product does not satisfy the requirements for nutritionally balanced food products.

The reference also teaches organic acids and vitamins including vitamin D as ingredients (lines 1-20 and 55-68 in column 5, lines 1-12 in column 6). See examples and claims.

Ascertaining the differences between the prior art and the claims at issue.

The reference does not teach the pH from 3 to 4 as presently claimed, the reference teaches that "It is necessary that the protein form an isoelectric gel at the pH of the food product of the invention, i.e., pH 3.3 to 4." The reference also does not teach directly plasma level increase however, it teaches the whey protein which is expected to increase plasma level.

DAVENPORT teaches use of colostrum supplement with whey protein concentrate or casein. It further teaches that plasma volume expands with

colostrum intake (see the entire document especially abstract, first para in column 2, 5th paragraph on page 2815 (cited below) and table 1 on page 2816).

> The hourly profile of plasma IgG (Figure 1) indicated increasing IgG in plasma of all calves to approximately 8 to 12 h; thereafter, IgG concentrations did not increase markedly or were constant. Apparently, absorption of ingested IgG was complete or movement of circulating IgG to extravascular pools had equilibrated with absorption of IgG by approximately 12 h. Changes in plasma IgG hourly profiles to 24 h in calves fed WPC were greater ($P < 0.006$) than those in calves fed C-0 (Figure 2). Calves fed W-200 and W-400 consumed 6 and 12 g of IgG from WPC, respectively, in addition to IgG from CS. Assuming an AEA of 30% for IgG from CS (Table 1), it is possible to estimate AEA of IgG from WPC. For calves fed 6 and 12 g of IgG, the AEA of additional IgG from WPC were 58 and 45%, respectively. These AEA are higher than other AEA data in this experiment; therefore, the absorption of IgG from the added WPC was not impaired by the additional protein.

Colostrum is breast milk so it contains natural calcium, carbohydrates, fat and water. The reference teaches the combination of whey protein and casein.

Yoshie et al. (JP 2001-346528) teaches preparation of gelatinous food see the entire document especially abstract, [00060]], [0010] ,[0021] and [0023]. The reference teaches gelling food containing protein, calcium fruit juice. The reference teaches **pH from 3 to 7.5** (see [0021].

[0021]The above-mentioned gel formation is produced on an acidity - neutral region, and concrete target in the large pH range of pH 3-7.5. It is preferably desirable the range of abbreviation pH 4.5-7.2 and to make gel form still more preferably in the neutral region of abbreviation pH 6.5-7.2. It is because acid agglutination may happen and it may not become uniform gel, although gel formation is carried out under acidity to uniform and smooth good gel being obtained if gel formation is carried out under neutrality.

Mamoru et al. (JP 07-322817) teaches preparation of food using whey protein. See the entire document especially abstract, claims, [0009], [0034], [0028] and [0038]. The reference teaches the food in the form of noodle or noodle like-gestatlt like thin wheat noodles containing whey protein, gelling agent, milk, dairy products, pulp, whey powder and dairy product.

[0009]In a manufacturing method of this invention, a starting material Beast milk, fermented milk, a cheese head, solid yogurt, They are what (it may be indicated as the raw material concerned below) liquefied powdered milk, casein, whey, whey protein concentrates (what is called WPC, WPI, etc. are included), or these mixtures, the thing which added soybean milk, wheat flour, etc. suitably in the raw material concerned, etc.

[0034]To 13.0 kg of soybean milk (10.2% of solid content) prepared by adding, grinding and boiling water to the soybean which immersed in working example 3 water, and removing tofu lees, 4.0 kg of whey protein concentrates (WPI: made in Mirai), 0.2 kg of trisodium citrate (made by San-Ei Gen FFI), 5.0 kg of starch (made by the Matsutani chemicals company), 1.0 kg of sodium alginate (made by KIBUN FOOD CHEMIFA CO., LTD.), 0.5 kg of xanthan gum (made by San-Ei Gen FFI) and 76.3 kg of water were added, and it mixed uniformly, and it heat-treated for 10 minutes, and where a safety catch board is hit to a pars basilaris ossis occipitalis, these 80 ** of mixtures were put into the extrusion molding apparatus which drilled many holes 1.0 mm in diameter in the pars basilaris ossis occipitalis.

Resolving the level of ordinary skill in the pertinent art and considering objective evidence present in the application indicating obviousness or nonobviousness.

It would have been obvious to one skilled in the art at the time of invention to prepare a nutritional supplement containing a protein which does not coagulate at 3.3 to PH 4 (whey protein, as in the disclosure of the present invention and colostrum) and vitamin D and other ingredients in the form of a gel, JP 2001-346528 teaches pH range 3 to 7.5 (which overlaps presently claimed pH), even pH of the same range is not taught as in Emoto which teaches 3.3 to 4 the expected pH may be 3 to 4 because the same ingredients will have similar pH (no unexpected results are shown by selecting a particular range). Prior art teaches the nutritional supplement and food compositions and process of making them in the form of a gel. One skilled in the would know that calcium in natural from, acids, carbohydrates, fat and water all are present in milk which expands plasma volume. One skilled in the art would also know to add emulsifying agent and agar because prior art also teaches the use of these components. Motivation has been provided by the reference. Therefore, providing the composition one would expect the

increase in plasma level as has been taught by Davenport and has been presently claimed. Since no new concept and/or improvement were noted therefore presently claimed invention has been considered obvious over the prior art of record.

The proportions and percentage are taught by the references. Even if these were not in the ranges court has decided that normally, change in temperature, concentration, or both, is not a patentable modification; however, such changes may impart patentability to a process if the ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from results of prior art; such ranges are termed "critical" ranges, and applicant has burden of proving such criticality; even though applicant's modification results in great improvement and utility over prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art; more particularly, where the general conditions of the claim are disclosed in the prior art, it is not inventive to discover optimum or workable ranges by routine experimentation. In re Aller et al. 105 USPQ 233. The formulation as gel would have been obvious to one who is familiar with the art.

It is well established that merely selecting proportions and ranges is not

patentable absent a showing of criticality. In re Becket, 33 U.S.P.Q. 33 (C.C.P.A. 1937). In re Russell, 439 F.2d 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971).

One would expect increase in plasma volume when the composition containing similar components will be given to a subject. The activity and/effect of the composition is expected to be the same i.e. increase in plasma volume as has been claimed. Since no criticality and/or unexpected results are seen presently claimed invention is considered obvious over the prior art of record. In absence of any unexpected results presently claimed invention is considered prima facie obvious to one skilled in the art at the time the invention was filed.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the

conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an

invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10, 11, 13-15 and 18-20 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 7 of copending Application No. 10/525,385 in view of Ohkuma et al. (US Patent 5,364,652). Ohkuma teaches food products comprising about 3.3% to about 52.5 % indigestible dextrin (Abstract, Examples 5-53) and that indigestible dextrin is a good source of dietary fiber.

Claims of the copending application are drawn to as follows:

1. **(currently amended):** A gel composition for protein and calcium supplementation comprising the following components and having a pH in the range of 3 to 4:

Protein ~~or its hydrolysate~~ that does not coagulate at pH 3 to pH 4	5.5 - 8 wt.%
Calcium	0.1 - 0.5 wt.%
Acidulant	0.5 - 3 wt.%
Carbohydrate	4 - 20 wt.%
Fat	0 - 5 wt.%
Emulsifying agent	0 - 0.5 wt.%
Agar	0.1 - 1 wt.%
Guar gum or gellan gum	about 0.05 – about 0.3 wt.%
A masking component including(a) fruit juice and (b) hard-to-digest dextrin or hydrogenated hard-to-digest dextrin	0.1 - 20 wt.%, and
Water	65 - 90 wt.%,

wherein the protein ~~or its hydrolysate~~ that does not coagulate at pH 3 to pH 4 is a combination of (A) whey protein concentrates or whey protein isolates, and (B) proteingelatin hydrolysates having a number average molecular weight of 500 to 10,000.

Present claims differ from the present application in containing masking agent.

Ohkuma et al. US'652 teaches dextrin as a component.

It would have been obvious to one skilled in the art at the time the invention was filed to prepare a gel composition containing protein, calcium, acids, guar gum,

carbohydrates and a masking agent. Use of masking agents has been taught by Ohkuma reference. The property of increase in plasma volume is expected to be present when the composition containing the same ingredients will be given to a subject. Detailed reasons are cited above.

In absence of any unexpected results present invention is considered obvious on claims of co-pending application 10/525,385 for reasons cited above.

This is a provisional obviousness-type double patenting rejection.

Response to Remarks

Applicant's response filed on 01/03/11 arguments is hereby acknowledged. Arguments have been fully considered but are not found persuasive. Following reasons apply:

JP 2001-346528 (English translation) and JP 07-322817 (English translation)

Applicant argues that there are no explanations for JP '528 and JP 817. Examiner disagrees because it is described on page 9 of the office action that JP 2001-346528 teaches preparation of gelatinous food and JP 07-322817 teaches preparation of food using whey protein. The references to various paragraphs were made for further teachings. However, more explanation has been added.

EMOTO, MITSUO (US Patent 6,458, 395)

Applicant argues that Emoto does not teach pH, MW of protein, therefore, Emoto teaches away.

Examiner disagree because it teaches pH 3.3-4, protein coagulate at 3.3 , not at 3.0, as claimed, so Emoto does not teach away and MW as claimed is broad encompassing almost all molecular weight. No unexpected results from any specific MW are disclosed. No unexpected results are disclosed.

Applicant argues that amended claims are not obvious over EMOTO because it fails to teach the protein which does not coagulate at pH 3.3 to 4 and also fails to teach protein hydrolysate of average molecular weight 5000-10,000.

Examiner disagrees because the average molecular cut off has not been shown to be critical in the present invention. No unexpected results are noted. Examiner disagrees because EMOTO teaches (1) whey protein which has been claimed and disclosed in specification.(therefore expected to have the molecular wt the same as claimed (2) it further suggests that a gelling agent may be employed for the formation of the beverage gel. As a result it would be obvious to one skilled in the art, that if a protein that **does not coagulate at low pH is employed**, a gelling agent can be used to impose the gelling properties of the gel beverage.

On the other hand, employing protein hydrolysates which do not coagulate at low pH is obvious to one skilled in the art. The increase in plasma level will be expected by giving the similar food in gel form.

DAVENPORT et al. (J. Dairy Sci. 83:2819; 892 reference)

Applicant argues that Davenport: does not remedy Emoto and does not teach pH or MW as presently claimed. Examiner disagrees because Davenport reference is relied upon for the solely teaching of expansion of plasma protein using whey protein concentration.

Applicant argues that presently claimed invention is not prima facie obvious Examiner disagrees because the present invention as a whole is taught by the combination of the prior art references. The rejection has been made on combination of references. "One cannot show nonobviousness by **attacking references individually** where the rejections are based on combinations of references." See In re Keller, 642 F.2d 413, 208 SPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145.

It has been decided by the court that "when a patent simply arranges old elements with each performing the same function it had been known to perform

and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S, Ct. 1727, 1740 (2007) (quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is… a person of ordinary creativity, not an automaton." Id. at 1742.

See In re Levin, 84 USPQ 232, In re Benjamin D. White, 17 C.C.P.A. (Patents) 1144, 156 F, 2d 189, 70 USPQ 221.

Using the same components as taught by the prior art, the effect of the composition is expected to be inherent and will increase plasma volume, plasma total protein content and plasma albumin content as has been claimed. The increase in plasma level has been taught by Davenport reference.

In absence of any unexpected results presently claimed invention would have been obvious to one skilled in the art at the time the invention was filed.

Co-pending Applications

Application number 10/534,734 is abandoned. Application number 10/525,385 is pending.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fetterolf Brandon can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/

Primary Examiner, Art Unit 1628